

vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents> or <https://www.regulations.gov>.

Dated: September 2, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–1263]

Submitting Documents Using Real-World Data and Real-World Evidence to the Food and Drug Administration for Drug and Biological Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled “Submitting Documents Using Real-World Data and Real-World Evidence to FDA for Drug and Biological Products.” To facilitate FDA’s internal tracking of submissions to the Agency that include real-world data (RWD) and real-world evidence (RWE), this guidance encourages sponsors and applicants to identify in their submission cover letters certain uses of RWD/RWE. This guidance does not address FDA’s substantive review of the RWD/RWE submitted as part of the Agency’s standard review process. This guidance finalizes the draft guidance entitled “Submitting Documents Using Real-World Data and Real-World Evidence to FDA for Drugs and Biologics” issued on May 9, 2019.

DATES: The announcement of the guidance is published in the **Federal Register** on September 9, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to [https://](https://www.regulations.gov)

www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2019–D–1263 for “Submitting Documents Using Real-World Data and Real-World Evidence to FDA for Drug and Biological Products.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available

for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Raymond Chiang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2232, Silver Spring, MD 20993–0002, 301–796–1940; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled

“Submitting Documents Using Real-World Data and Real-World Evidence to FDA for Drug and Biological Products.” As one mechanism to inform FDA’s RWE program under the 21st Century Cures Act (Pub. L. 114–255), and specifically to help FDA understand the scope and use of RWD/RWE submitted to support regulatory decisions regarding safety and/or effectiveness, the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), and the Oncology Center of Excellence (OCE) track certain types of submissions involving RWD/RWE. As described in this guidance and to promote consistency in this effort, CDER, CBER, and OCE encourage sponsors and applicants to identify whether their submissions include certain uses of RWD/RWE. To assist FDA in tracking of RWD/RWE submissions, FDA recommends that the sponsor or applicant include the following information in their cover letter: (1) purposes of using RWD/RWE, (2) study designs using RWD to generate RWE, and (3) RWD sources used to generate RWE.

This guidance finalizes the draft guidance entitled “Submitting Documents Using Real-World Data and Real-World Evidence to FDA for Drugs and Biologics” issued on May 9, 2019 (84 FR 20368). FDA considered comments received on the draft guidance as the guidance was finalized, and changes were made to improve clarity.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Submitting Documents Using Real-World Data and Real-World Evidence to FDA for Drug and Biological Products.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of

information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: September 6, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Intent To Make Temporary Changes in the State Title V Maternal and Child Health Block Grant Allocations

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Response to solicitation of comments.

SUMMARY: HRSA plans to move forward in implementing temporary changes to the method of calculating poverty-based allocations under Title V of the Social Security Act for HRSA’s State Title V Maternal and Child Health (MCH) Services Block Grant, beginning in Fiscal Year (FY) 2023. Since FY 2017, the poverty-based allocation has been based on the U.S. Census Bureau’s 3-year American Community Survey (ACS) estimates using three pooled 1-year estimates. However, due to the COVID–19 pandemic, there were disruptions in the ACS data collection in 2020 resulting in data quality issues that prevented the Census Bureau from releasing standard 1-year ACS estimates; instead, the Census Bureau released experimental estimates. The ACS 2020 experimental estimates will be excluded from calculating Title V MCH Services Block Grant allocations, and the FY 2023 funding allocation will be based on the same poverty data used in the FY 2022 allocation (*i.e.*, pooled 1-year

estimates for 2017, 2018, and 2019 ACS). Funding allocations for FY 2024 and FY 2025 will continue to incorporate the latest 1-year ACS data while skipping 2020 (*i.e.*, for FY 2024, the 2018, 2019, and 2021 ACS data will be used; for FY 2025, the 2019, 2021, and 2022 ACS data will be used). In FY 2026, the temporary change to the method for calculating allocations will no longer be necessary, and HRSA will resume pooling of three consecutive 1-year estimates (2021–2023).

DATES: *Effective Date:* October 1, 2022.

FOR FURTHER INFORMATION CONTACT:

Christopher Dykton, Acting Director of the Division of State and Community Health, Maternal and Child Health Bureau, HRSA, Room 18N35, 5600 Fishers Lane, Rockville, Maryland 20857; telephone: (301) 433–2204; email: MCHBlockGrant@hrsa.gov.

SUPPLEMENTARY INFORMATION: Beginning in FY 2023, HRSA will temporarily change the method of calculating the poverty-based allocation to States and the District of Columbia under section 502(c) of Title V of the Social Security Act (42 U.S.C. 702(c)). Because of data collection disruptions due to the COVID–19 pandemic, the Census Bureau did not release standard 1-year ACS estimates for 2020. Survey administration methods (mailed questionnaires and interviewing in-person) were impacted beginning in March 2020, which affected response rates, in terms of who was most likely to complete mailed surveys or participate in interviews, etc.¹ The Census Bureau concluded that the 2020 ACS 1-year data were not “reasonable” as respondents disproportionately “had higher levels of education, had more married couples and few never married citizens, had less Medicaid coverage, had higher median household incomes, and fewer non-citizens, and were more likely to live in single-family housing units” than respondents in previous years. Instead, the Census Bureau decided to provide only experimental estimates for 2020 ACS 1-year data.²

HRSA examined the 2020 ACS experimental estimates and compared the change in poverty share using a 3-

¹ https://www.census.gov/library/working-papers/2021/acs/2021_CensusBureau_01.html.

² The Census Bureau defines experimental data products as “innovative statistical products created using new data sources or methodologies that benefit data users in the absence of other data products Census Bureau experimental data may not meet all of HRSA’s data quality standards. Because of this, HRSA clearly identifies experimental data products and includes methodology and supporting research with their release.” <https://www.census.gov/data/experimental-data-products.html>.